

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING	)	
PHARMACY, INC. PRODUCTS LIABILITY	)	
LITIGATION	)	
_____	)	MDL No. 2419
	)	Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO:	)	
	)	
Suits Naming the Tennessee Clinic	)	
Defendants	)	
	)	

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**TENNESSEE CLINIC DEFENDANTS' RESPONSE TO  
THE PSC'S MOTION FOR ENTRY OF CASE MANAGEMENT ORDER SETTING AN  
EXPEDITED TRIAL DATE [DKT. 1716]**

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Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD (collectively "Tennessee Clinic Defendants" or, at times herein, the "Defendants") respond in opposition to the PSC's *Motion for Entry of Case Management Order Setting an Expedited Trial Date* (hereinafter, at times, the "Motion").<sup>1 2</sup> This Response also includes a preliminary proposed bellwether framework, as contemplated by Magistrate Judge Boal's Order No. 9 (*Order Regarding Common Issue Discovery*).<sup>3</sup>

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<sup>1</sup> Dkt. 1716.

<sup>2</sup> The "Tennessee Clinic Defendants" are actually three sets of defendants in cases filed across Tennessee. Cases have been filed against (1) the Nashville clinic (STOPNC) and related entities and providers (Howell Allen; Dr. Culclasure; Ms. Schamberg); (2) the Crossville clinic (SSC) and related entities and persons (Kenneth Lister, MD; Kenneth Lister, MD, PC); and (3) a physician in Oak Ridge (Dr. Jones). The PSC's Motion requests an expedited trial of six cases against the Nashville clinic (STOPNC) and its related entities and providers (Howell Allen; Dr. Culclasure; Ms. Schamberg). This Response is filed on behalf of the STOPNC-related Tennessee Clinic Defendants but also notes that a similar process should be put in place to ensure that three representative SSC-related cases are tried in the same timeframe, and the Response suggests potential SSC bellwethers.

<sup>3</sup> Dkt. 1425.

## **1. Introduction**

The Defendants share the PSC's interest in moving these cases efficiently and agree that a small subset of cases should be tracked toward trial. However, the process must ensure that the litigants are adequately prepared for trial after full and fair discovery; and, to be worthwhile, the cases selected for the initial trials must be representative in order to provide predictive value.

The PSC proposes to nullify Judge Boal's September 18, 2014, *Order Regarding Common Issue Discovery*<sup>4</sup> in favor of a single trial of six (6) PSC-selected outlier cases. The PSC's proposal is neither realistic nor fair, nor is it consistent with the accepted recommendations for managing complex mass tort litigation. The PSC's plan to try six (6) non-representative cases in a consolidated trial – with liability tried once and damages tried six (6) times in one setting – is a thinly-veiled attempt to obscure the liability issues with the six (6) most compelling tales of personal loss.

In order to try six (6) outlier cases during the Christmas holiday, the PSC also proposes an unworkable discovery schedule which ignores the realities of the litigation. A desire to ready a case in 2015 cannot override the MDL Court's responsibility to ensure representative bellwether cases are fully prepared and fairly tried.

This Response addresses two aspects of the PSC's Motion – first, timing and, second, the process of selecting cases. The Response explains why the PSC's proposal fails to present a reasonable timetable or fair process, and proposes a much more sensible alternative.

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<sup>4</sup> Dkt. 1425 (September 18, 2014).

## 2. Procedural history

### a. Judge Boal's Order Regarding Common Issue Discovery

As the PSC admits in its brief, the cases against the Tennessee Defendants did not begin “in earnest” until the Court ruled on the global motions to dismiss on August 28, 2014.<sup>5</sup> At that point, with the surviving legal claims identified, the parties had the initial discovery conference, and Judge Boal entered the initial order governing discovery in these cases.<sup>6</sup> With the discovery plan in place, the litigation began.<sup>7</sup>

Judge Boal did not simply plug dates into a form order to create the *Order Regarding Common Issue Discovery*. That Order was the result of extensive briefing spanning many months and oral argument. The *Order Regarding Common Issue Discovery* was designed to (1) move the parties through Common Issue Discovery and (2) put in place a bellwether process to select representative cases for case-specific discovery and trial. While the Tennessee Clinic Defendants did not agree with every aspect of Judge Boal's Order, it was certainly well considered, and it set forth a reasonable timetable for the parties to conduct discovery and propose bellwethers.

Since that time, the parties have engaged in discovery in compliance with the Order. This began with production of the individual Plaintiff Profile Forms,<sup>8 9</sup> moved

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<sup>5</sup> The PSC states several “facts” in its Motion that are, at best, half-truths. For instance, at page 7, it states that prior to Judge Boal's Order the Tennessee Clinic Defendants “largely refused to participate in discovery.” This is demonstrably false. The PSC filed these cases first in state court. The Tennessee Clinic Defendants responded to over 200 interrogatories and 50+ requests for admission and produced approximately 1,000 documents. That is hardly “refus[ing] to participate in discovery.” The Tennessee plaintiff lawyers strategically chose to voluntarily dismiss the state court cases, which were tracking toward trial, in favor of pursuing the MDL route.

<sup>6</sup> Dkt. 1425 (September 18, 2014).

<sup>7</sup> September 18, 2014, is the date that the cases commenced for evaluating the true “age” of the cases.

<sup>8</sup> In a format approved by Judge Boal after briefing and argument.

<sup>9</sup> The PSC wants to rocket cases to trial, but the Plaintiffs have not even produced all PPFs. Additionally, the PSC's responses to these Defendants' written discovery requests were, at times, evasive at best, sanctionable at worst. For instance, the Plaintiffs refuse to even admit that NECC owed the Plaintiffs a

through written discovery, and the parties are now well into the depositions of the Tennessee parties and written discovery of comparative fault parties, with the depositions of comparative fault parties and fact witnesses to follow. In short, Judge Boal's plan has worked. There is no reason to abandon it now.

### **b. Present status of discovery**

The following charts capture the status of discovery now and the discovery remaining before the cases will be ready for trial.

#### **Common Fact Discovery – conducted and remaining**

<u>Party<sup>10</sup> / Non-Party</u>	<u>Written discovery done</u>	<u>Depositions completed</u>	<u>Discovery left to be done</u>
Plaintiffs	ROGs, RFPs, RFAs answered	None	Motion practice on sufficiency of PSC's responses <sup>11</sup>
TN Clinic Defendants	ROGs, RFPs, RFAs answered; ESI done	Three STOPNC; two SSC completed	No additional depositions requested or scheduled <sup>12</sup>
St. Thomas Entities	ROGs, RFPs, RFAs answered; ESI done	None	Depositions of four St. Thomas witnesses set in April
UniFirst	Written discovery issued and now outstanding	None	Written discovery to be answered + will take ~2-3 depositions
Ameridose <sup>13</sup>	Written discovery issued and now outstanding	None	Written discovery to be answered + ~1 deposition
ARL <sup>14</sup>	Written discovery issued and now outstanding	None	Written discovery to be answered + ~1-2 depositions
MSM <sup>15</sup>	Written discovery issued and now outstanding	None	Written discovery to be answered + ~1-2 depositions
GDC <sup>16</sup>	Written discovery issued and now outstanding	None	Written discovery to be answered + ~0-1 depositions
Barry Cadden	Written discovery issued and now outstanding <sup>17</sup>	None	Written discovery to be answered, depo <sup>18</sup>

duty (despite alleging exactly that in the Complaints) and refuse to admit the median time the FDA takes to respond to a FOIA request (despite it being published on the FDA's website and attached to the request to admit). See examples of the PSC's non-responsive discovery responses attached as Exhibit 1.

<sup>10</sup> Some of these parties have reached settlements in the bankruptcy. However, they are still defendants in the Tennessee cases proposed for trial. Even if the bankruptcy plan has been approved by the time of a Tennessee trial, discovery of these entities and persons must still be conducted to support comparative fault defenses. Despite what the PSC suggests and what the settling parties may want, the settling parties are not relieved of all involvement once the bankruptcy plan is confirmed.

<sup>11</sup> See *supra* note 9.

<sup>12</sup> The Tennessee Clinic Defendants have asked the PSC whether it wishes to take additional depositions, but the inquiry has gone unanswered. The PSC likewise ignored the request that argument be held on these issues until all parties briefed their positions. See letter and related emails attached as Exhibit 2.

<sup>13</sup> NECC's sister company, owned and controlled by the same principals.

<sup>14</sup> The company that tested the contaminated product, certifying it as "sterile."

<sup>15</sup> The marketing arm of NECC (owned and controlled by the same principals), which represented to the Tennessee Clinic Defendants that NECC's product was of the highest standards.

<sup>16</sup> The owner of the property where NECC conducted its operations.

<u>Party / Non-Party</u>	<u>Written discovery done</u>	<u>Depos completed</u>	<u>Discovery remaining</u>
Doug Conigliaro	Written discovery issued and now outstanding	None	Written discovery answered + deposition
Lisa Cadden	Written discovery issued and now outstanding	None	Written discovery answered + deposition
Carla Conigliaro	Written discovery issued and now outstanding	None	Written discovery answered + deposition
Glenn Chin <sup>19</sup>	Written discovery issued and now outstanding	None	Written discovery answered + deposition
NECC <sup>20</sup>	Written discovery and oral discovery expected	None	Written discovery answered + ~2-4 depositions
Liberty	Written discovery issued and some documents produced	Two	Written discovery answered + 0-1 depositions
Alaunus	Written discovery issued and now outstanding	None	Written discovery answered + 0-1 depositions
FDA	Has responded to FOIA but has not responded to subpoena; 30(b)(6) issued	None	Deposition set in May
MA BoP	Has responded to public records request; 30(b)(6) issued	None	Deposition set in May
Scientific Air Analysis <sup>21</sup>	Has responded to subpoena <i>duces tecum</i>	None	Deposition
Brigham & Women's <sup>22</sup>	Has responded to subpoena <i>duces tecum</i>	None	Deposition

Thus, the total common fact discovery remaining is (a) written discovery of eleven parties and (b) 20-28 depositions.<sup>23</sup>

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### **Common Expert Discovery – depositions of common experts expected**

<u>Party<sup>24</sup></u>	<u>Estimated number of experts<sup>25</sup></u>
Plaintiffs	8-10 <sup>26</sup>
TN Clinic Defendants	8-10
St. Thomas Entities	6-8
UniFirst	3-5

Thus, the total common expert discovery left to be undertaken includes (in addition to completing reports for each expert) 25-33 expert depositions.

<sup>17</sup> Some discovery has been issued to NECC. The Tennessee Clinic Defendants plan to do so shortly.

<sup>18</sup> Discovery of NECC and its owners and affiliates will be disputed. The affiliates will resist discovery because they have settled the claims against them in principle and will also resist on Fifth Amendment grounds. Court intervention will likely follow. This will only add to the time required for common discovery.

<sup>19</sup> The pharmacist who compounded the batches at issue.

<sup>20</sup> NECC is not a party to the Tennessee cases, but discovery of NECC (the main actor in these suits) will have to occur to support comparative fault defenses.

<sup>21</sup> Performed air testing of NECC's facility in 2012.

<sup>22</sup> Performed a site visit of NECC in 2012.

<sup>23</sup> In *Wingate*, the first of the Virginia cases readied for trial, the parties conducted 19 depositions of fact witnesses and conducted very little comparative fault discovery. Thus, the estimate of 20-28 remaining common fact discovery depositions is a reasonable projection.

<sup>24</sup> This assumes that no settling defendant will participate in trial. At this point, the settling defendants are still *defendants* in the proposed trial cases, with no order dismissing them expected in the near future.

<sup>25</sup> The numbers for the St. Thomas Entities and UniFirst are simply estimates. These numbers have not been discussed with those Defendants. The number for the Plaintiffs is also an estimate.

<sup>26</sup> In *Wingate*, the Plaintiff disclosed 13 experts. Thus, this number is not exaggerated. Counsel asked the PSC how many experts it will disclose. The question was ignored. See Exhibit 2.

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**Case-Specific Discovery – fact witness and expert depositions expected**

Note: In case-specific discovery, the Defendants will take the depositions of the individual Plaintiffs and any case-specific fact witnesses (e.g., a family member). Each party will also likely disclose a small number of case-specific experts (e.g., a causation witness or damages witness specific to the individual case issues):

<b><i>Party</i></b>	<b><i>Estimated number of fact depositions</i></b>	<b><i>Estimated number of experts</i></b>
Plaintiffs	4-8 <sup>27</sup> (depending on number of bellwether cases)	1-2
TN Clinic Defendants	None	1-2
St. Thomas Entities	None	1-2
UniFirst	None	1-2

**Thus, the total case-specific fact and expert discovery remaining to be scheduled and completed includes at least (a) 4-8 fact depositions and (b) 4-8 expert depositions.**

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These estimates are just that, but they are not exaggerations. If anything, this Response is a conservative illustration of the discovery still necessary before any individual case is ready for trial.

The PSC would like the Court to believe that the settlements reached by the National and Affiliated Defendants reduce the amount of required discovery. However, the only real change resulting from the settlements is who will be conducting that discovery. Now, the non-settling defendants (e.g., the clinic defendants) – not the PSC – will be responsible for discovery to prove the allegations against the settling parties.<sup>28</sup>

All told, before the first subset of case is ready for trial, in addition to the outstanding written discovery, 50-75 depositions remain to be scheduled and

<sup>27</sup> Assuming four STOPNC bellwether trial cases, with the Plaintiff and one fact witness deposed in each.

<sup>28</sup> Importantly, the PSC has had access to thousands upon thousands of documents from the National and Affiliated Defendants for many months, access these Defendants have not had. For instance, 28,000 ARL documents are only now being made available to the Defendants after motions heard at the March status conference. The PSC has had these documents for approximately two years.

completed. The PSC's proposal to complete this process in the next six (6) months is simply not feasible, *unless written discovery and depositions of parties and key witnesses are simply omitted*, assuring incomplete consideration of the issues.

### 3. Timing

#### a. Examples of the absurdity of the PSC's proposal and two (2) proxies

Concrete examples demonstrate the unworkable timing of the PSC's proposal:

- The proposal offers 30 days to depose common expert witnesses. As explained above, this will likely be 20-30 expert witnesses.
- The proposal forecloses *any* time for case-specific discovery. There is no time allotted for case-specific fact discovery (e.g., written discovery and depositions of the Plaintiffs and their family members; depositions of each Plaintiff's treating health care providers), or case-specific expert discovery (e.g., reports and depositions of case-specific damages experts).
- The proposal includes nine (9) business days (9/1/15-9/15/15) to file *Daubert* motions *and* summary judgment motions at the end of common expert discovery.
- The summary judgment process is allotted approximately 45 days from start to finish.<sup>29</sup> This process took almost a year at the motion to dismiss stage.

Two (2) proxies illustrate the absurdity of the PSC's proposal, and also offer experience-based guidance.

*Wingate*<sup>30</sup> was the first of the Virginia cases, tracked through state court toward trial. *Wingate* involved a single plaintiff and two health care provider defendants. The PSC acknowledges that *Wingate* moved rapidly.<sup>31</sup> From filing of the Complaint to the *scheduled* trial, the litigation was scheduled to span 16 months.

<sup>29</sup> There are several key legal issues that will be tested at the summary judgment stage, namely the viability of the product liability claim and the viability of the agency claim against the St. Thomas Entities.

<sup>30</sup> *Wingate v. Insight Health*, et al., No. CL 12-2547, Circuit Court of City of Roanoke.

<sup>31</sup> Dkt. 1189.

By comparison, the PSC proposes a schedule from the initial discovery order (9/18/14) through preparation of six cases to trial (12/4/15) of 14½ months, *less* than the much simpler *Wingate* case. If *Wingate* moved “rapidly,” the PSC expects the six (6) Tennessee cases proposed for trial to move at a breakneck pace.

The PSC points to the *Granuflo* litigation in this District as support for the “Six by Christmas” proposal. *Granuflo* is not comparable. There is a single corporate defendant (Fresenius) facing allegations of harm related to its product. The initial scheduling order was entered October 1, 2013.<sup>32</sup> An April 8, 2014, CMO set a bellwether protocol.<sup>33</sup> A June 6, 2014, CMO set the first bellwether trial for January 11, 2016.<sup>34 35</sup>

The *Granuflo* court adopted a timeline of 2+ years from the initial discovery order (10/1/13) to first bellwether trial (1/11/16). The PSC’s proposal cites *Granuflo*’s timeline – a simpler case without the complicating factors of concurrent bankruptcy and criminal proceedings – *but proposes a timeline here that is half that contemplated in Granuflo*.<sup>36</sup> Notably, applying the *Granuflo* timeframe to the *NECC* litigation, the first bellwether trials would be in early-2017 (a little over two years from the *NECC* initial discovery order), *exactly what these Defendants propose*.

Every lawyer is an optimist, convinced that discovery will take less time than reality demands. Rather than set unreasonable deadlines and repeatedly seek

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<sup>32</sup> Case 1:13-md-02428-DPW, Dkt. 334.

<sup>33</sup> Case 1:13-md-02428-DPW, Dkt. 583.

<sup>34</sup> Case 1:13-md-02428-DPW, Dkt. 635.

<sup>35</sup> This appears to be delayed due to problems with bellwether selection.

<sup>36</sup> A chart illustrating this comparison is attached as Exhibit 3.



extensions<sup>37</sup>, the Tennessee Clinic Defendants propose an alternative, reasonable timeline for completing the work necessary before trials of truly representative cases.

**b. Proposed timeline**

The PSC's proposal ignores the time required to complete each task, instead proposing a trial date in December 2015, and forcing dozens of outstanding tasks into the remainder of 2015. It is ill-advised to simply accept the PSC's demand that a case be tried in 2015 without considering the amount of time each step requires. The Tennessee Clinic Defendants propose the following *reasonable* timeline to bring these cases to trial by the end of 2016 or early-2017:

<b><u>Phase</u></b>	<b><u>Task</u></b>	<b><u>Deadline</u></b>	<b><u>Comment</u></b>
<b>Bellwether plan development</b>	Deadline to meet and confer on bellwether proposals	5/15/15	This is extended 30 days from Judge Boal's present discovery order to allow for common discovery left to complete.
	Deadline to submit bellwether proposals	6/15/15	This is consistent with Judge Boal's present order, extended 30 days to allow for common discovery left to complete.
<b><i>*Note: Between 6/15/15-8/15/15, based on the parties' submissions, Judge Boal would put in place a bellwether selection protocol.<sup>38</sup> The protocol would be in place before the parties complete common fact discovery and would lead into common expert discovery and individual case discovery.</i></b>			
//////////	*Completion of common fact discovery*	8/18/15	These deadlines are extended 60 days from Judge Boal's present discovery order to allow for the extensive common discovery remaining.
<b>Common expert discovery</b>	Plaintiffs' common expert disclosures	9/18/15	
	Defendants' common expert disclosures	10/19/15	
	Deadline to depose common expert witnesses	1/18/16	This is extended 30 days because of the number of expected expert depositions.

<sup>37</sup> In this litigation, the PSC has repeatedly sought aggressive deadlines that proved untenable. See, e.g., *Motion for Extension of Time to File Mediation Order* [Dkt. 363]; *Request for Extensions to File Master Complaint and Short Form Complaint* [Dkt. 395]; *Motion to Extend Deadlines in Previous CMO and to Revise CMO* [Dkt. 421]; *Motion to Extend Deadlines Set Forth in Mediation Program* [Dkt. 487]; *Motion for Extension of Time to File Master Complaint as to Affiliated Defendants* [Dkt. 540]; *Motion to Extend Deadline for Filing List of Subpoena Recipients Named as Defendants* [Dkt. 574]; *Motion for Extension of Time to Respond to Traveler's Motion to Quash* [Dkt. 737]; *Motion to Extend Deadline for Filing Master Complaint Against Affiliated Defendants* [Dkt. 741]; *Motion for Extension of Deadline to Respond to Trustee's Renewed Motion to Transfer* [Dkt. 760]; *Motion for Additional Extension of Time to Respond to Traveler's Motion to Quash* [Dkt. 765].

<sup>38</sup> As discussed below, the Tennessee Clinic Defendants envision a bellwether process that results in selection of four (4) STOPNC cases for trial. The parties will conduct case-specific discovery in these four (4) cases, preparing each for trial. This suggestion differs slightly from the Tennessee Clinic Defendants' initial proposal at Dkt. 1258 (see 1258-15). There, the Tennessee Clinic Defendants proposed case-specific discovery in a trial pool of 16 cases, from which the four (4) bellwethers would be selected. Here, the Tennessee Clinic Defendants streamline that proposal and skip the "pool" stage, instead simply selecting four (4) bellwethers for case-specific discovery and trial. (These Defendants envision three (3) SSC cases following the same selection process.)

***\*Note: At this point, the parties will have completed common fact and common expert discovery. Additionally, the four (4) STOPNC bellwether trial cases will have been selected under Judge Boal's protocol. Having completed common fact and common expert discovery, the parties are positioned to enter into a Tennessee-specific mediation and to determine whether the Tennessee cases should be remanded for case-specific discovery and trial.***

<b><i>Phase</i></b>	<b><i>Task</i></b>	<b><i>Deadline</i></b>	<b><i>Comment</i></b>
<b>Case-specific fact discovery in four STOPNC bellwether trial cases</b>	Deadline to issue written discovery in four bellwether cases	2/15/16	This provides a short window after the close of common expert discovery to issue and answer short sets of written case-specific discovery and to depose the expected 1-2 fact witnesses in each of the four bellwether trial cases. <sup>39</sup>
	Deadline to respond to written discovery in four bellwether cases	4/1/16	
	Deadline to take depositions of Plaintiffs and fact witnesses in four bellwether cases	5/16/16	
<b>Case-specific expert discovery in four STOPNC bellwether trial cases</b>	Deadline for Plaintiffs to disclose case-specific experts	6/15/16	There will be several case-specific expert witnesses disclosed by each party on causation and damages. This provides about 100 days to disclose and depose them.
	Deadline for Defendants to disclose case-specific experts	7/15/16	
	Deadline to depose case-specific experts	9/1/16	
<b><i>*Note: At this point, common discovery in all cases and case-specific discovery in the four (4) trial cases is complete. The cases are ready for pre-trial motion practice and trial. This allows approximately 90 days to file dispositive motions and pre-trial motions.</i></b>			
<b>Trial of first STOPNC bellwether case</b>		December 1, 2016	
<b>Trial of second STOPNC bellwether case</b>		January 16, 2017	
<b>Trial of third STOPNC bellwether case</b>		February 15, 2017	
<b>Trial of fourth STOPNC bellwether case</b>		March 15, 2017	

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The preceding schedule sets the first bellwether for trial just over two (2) years from the initial discovery order.<sup>40</sup> While that may seem like a long time when considered in a vacuum, it is actually an ambitious schedule given the remaining material discovery in this complex case complicated further by a concurrent bankruptcy, ongoing criminal proceeding, a dozen defendants, and even more involved and interested lawyers.

### **c. Lexecon**

As stated at the March 25, 2015 status conference, the Tennessee Clinic Defendants do *not* waive their right under *Lexecon v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998) to have the cases tried in Tennessee.

<sup>39</sup> See, e.g., *Granuflo* Dkt. 583 (allowing case-specific discovery in bellwether cases).

<sup>40</sup> A diagram similar to that at 1258-15 showing, conceptually, the flow of the cases from now to the four (4) STOPNC bellwether trials under the proposal outlined in this brief is attached as Exhibit 4.

#### 4. Bellwether trial case selection

There can be no reasonable opposition to two points: One, truly representative bellwether cases should be tried because trying non-representative cases does nothing but take time and incur cost without yielding any predictive information. And, two, the cases proposed by the PSC are not representative.

##### a. The Court should order trial of *representative* cases

Judge Eldon E. Fallon has written extensively on management of this type of multi-district litigation.<sup>41</sup> While not authoritative, his advice should not be ignored. Judge Fallon's primary caution is to avoid a process that results in the trial of non-representative cases. Without representative bellwethers, "the transferee court and the attorneys risk trying an anomalous case, thereby wasting substantial time and money."<sup>42</sup>

The Manual for Complex Litigation agrees:

**If individual trials, sometimes referred to as bellwether trials or test cases, are to produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases...**Test cases should produce a sufficient number of representative verdicts and settlements to enable the parties and the court to determine the nature and strength of the claims, whether they can be fairly developed and litigated on a group basis[ ] and what range of values the cases may have if resolution is attempted on a group basis. **The more representative the test cases, the more reliable the information about similar cases will be.**<sup>43</sup>

Simply allowing one side to select its best cases – as the PSC proposes – is not a bellwether process and produces no representative, predictive results.<sup>44</sup>

<sup>41</sup> Fallon, *et al.*, *Bellwether Trials in Multidistrict Litigation*, TULANE LAW REV., Vol. 82, p. 2223 (2008).

<sup>42</sup> Fallon, 2344.

<sup>43</sup> *Manual for Complex Litigation, Fourth*, 360 (emphasis added) (internal cites omitted).

<sup>44</sup> *In re Chevron USA, Inc.*, 109 F. 3d 1016, 1019-20 (5<sup>th</sup> Cir. 1997) ("[w]hatever may be said about the trial contemplated by the district court's...order, one thing is clear. It is not a bellwether trial. It is simply a trial of fifteen (15) of the 'best' and fifteen (15) of the 'worst' cases contained in the universe of claims involved in this litigation").

**b. The cases selected by the PSC are not representative**

Review of basic, objective data establishes that the six (6) cases selected by the PSC are not representative of the entire pool of STOPNC cases. There are 117 patient Plaintiffs in the cases against STOPNC, with injuries categorized as<sup>45</sup>:

<b><u>Injury</u></b>	<b><u>Number</u></b>	<b><u>Percentage of all cases</u></b>
Death	14	12%
Meningitis + infection	44	38%
Meningitis only	19	16%
Local infection only (no meningitis)	13	11%
No disease	27	23%

Compare this to the PSC's trial proposals:

<b><u>Case</u></b>	<b><u>Type of injury</u></b>	<b><u>Comment</u></b>
<i>Reed</i>	Death	While death cases make up 12% of the total pool, the PSC proposes that death cases make up <u>33%</u> of the bellwether trial.
<i>Rybinski</i>	Death	
<i>Sullivan</i>	Meningitis + infection	The Defendants agree that including meningitis and/or "meningitis-plus" cases in the initial bellwether selections is appropriate.
<i>Wray</i>	Meningitis	
<i>McElwee</i>	Meningitis only	
<i>Ziegler</i>	Local infection only	The PSC proposes a single "infection only" case and <i>no</i> cases where the plaintiff had no disease despite these categories making up <u>34%</u> of the total pool of cases.

To be truly representative of the entire group of claims, a representative sample of injuries must be tried. The selected bellwether trial cases should include individual case(s) from each of the above categories ((1): death; (2) "meningitis-plus"; (3) meningitis only; (4) local infection only; (5) no disease). The PSC's proposed cases skew too much toward death cases and omit entirely the second largest group, the "no disease" category. In addition to skewing their selections toward the most serious injuries, the PSC unabashedly selected its "best" cases for each category. Consider:

**Reed**

- Diana Reed apparently injured herself caring for her husband, who has ALS. She had worked for a non-profit. She was 56-years-old and physically active prior to

<sup>45</sup> With a caveat that the Defendants are still receiving medical records to evaluate these factors.

her death. While incredibly sad and sympathetic<sup>46</sup>, this is simply not a representative Plaintiff. She is an outlier in age<sup>47</sup> and has a unique loss of consortium claim.

#### Rybinski

- Thomas Rybinski was 55-years-old and earning over \$100,000 at the time of his death. His lost earning capacity claim is for *over one million dollars*. Sixty percent of Plaintiffs make *no* lost earning claim. The median lost earnings claim is \$25,000. Mr. Rybinski's lost earning capacity claim is in the 96<sup>th</sup> percentile for these claims. This alone makes his case a significant outlier.<sup>48</sup>

#### Sullivan

- Ms. Sullivan is 70-years-old. While she is in line with the average age of the Plaintiffs, she has unique circumstances, too, with a *90-day hospitalization* that resulted in at least \$300,000 of medical expenses. Her medical expenses skew much higher than the average.<sup>49</sup>

#### Wray

- Jane Wray is 69-years-old. She had two hospital admissions. She is, at least, arguably representative of "meningitis-plus" patients.

#### McElwee

- Mr. McElwee is a 76-year-old former Marine. He was hospitalized for *80 days*. His medical expenses will undoubtedly skew much higher than average.

#### Ziegler

- Mr. Ziegler is 35-years-old, nearly half the age of the average Plaintiff. He is an Iraq War veteran. He is plainly non-representative of the pool.

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<sup>46</sup> See "After a Meningitis Death, Family Members Ask Why," N.Y. TIMES, at [http://www.nytimes.com/2012/10/11/health/after-a-meningitis-death-loved-ones-ask-why.html?\\_r=0](http://www.nytimes.com/2012/10/11/health/after-a-meningitis-death-loved-ones-ask-why.html?_r=0) (10/10/12); "In One Family's Tragic Meningitis Story, Support for More Policing of Pharmacies," PBS NEWSHOUR, at [http://www.pbs.org/newshour/bb/health-july-dec12-meningitis\\_11-14/](http://www.pbs.org/newshour/bb/health-july-dec12-meningitis_11-14/) (11/14/12).

<sup>47</sup> The average patient age for STOPNC Plaintiffs is 65; the median age is 66.

<sup>48</sup> Additionally, Mr. Rybinski's case is the *only* case where the fungus was *Aspergillus*. The remainder of the cases cultured a different fungus – *Exserohilum rostratum*. This has not been explained. See Smith, *et al.*, *Fungal Infections Associated with Contaminated Methylprednisolone Injections*, NEW ENGLAND JOURNAL OF MEDICINE, 2013; 369: 1598-1609 (October 24, 2013) ("[a] total of 153 case patients had evidence of *E. rostratum*, and 1 case patient had histopathological evidence of invasive disease due to *Aspergillus fumigatus*").

<sup>49</sup> Inclusion of Mr. Rybinski, Ms. Wray, and Mr. McElwee indicates an effort to present non-representative cases with high "hard" damages not present in most of the cases.

\* \* \* \* \*

The PSC made no effort to select representative cases for trial. The six (6) proposed for trial are the PSC's choice of the best of the 117 Plaintiffs. Trials of these non-representative, clear outliers assure the outcome Judge Fallon warns against.

**c. What is a representative case?**

The Tennessee Clinic Defendants propose selecting four (4) STOPNC cases and three (3) SSC cases for bellwether trials in late-2016 and early-2017, to be selected with the same general process and from the following categories<sup>50</sup>:

1. Death / Serious Injury (meningitis plus infection)
2. Meningitis or Local Infection Only
3. No Disease.

The SSC cases should be ready for trial in the same general timeframe. While the categorization is the same, the distribution of the 24 SSC cases is different than the STOPNC cases in some material respects.<sup>51</sup> Truly representative candidate cases that can be trusted to provide actual predictive value in the major categories include<sup>52</sup>:

**Death or Serious Injury**

STOPNC	SSC
Reba Temple	Patricia Gambaccini
Denis Brock	Wilma Carter
Joseph Pellicone	

<sup>50</sup> There are 24 SSC Plaintiffs that are on the same discovery track as the STOPNC cases and are less complicated given the absence of any allegations of vicarious liability. There is no reason representative SSC cases should not be included in the initial bellwether trial cases.

<sup>51</sup>

<b><u>Injury</u></b>	<b><u>Number</u></b>	<b><u>Percentage of all cases</u></b>
Death	3	13%
Meningitis + infection	2	8%
Meningitis only	4	17%
Local infection only (no meningitis)	4	17%
No disease	11	46%

<sup>52</sup> A summary of each proposed possible bellwether case is included with Exhibit 5.

Meningitis or Local Infection Only

STOPNC	SSC
Kelly Kirby	Jocelyn Norris
Mae Parman	
Reba Skelton	
Fredia Berry	

No Disease

STOPNC	SSC
Jon Kinsey	Wanda Dingess
Terry Pierce	John Johnson

**d. Consolidation as proposed by the PSC is inappropriate**

The PSC proposes combining their six (6) non-representative cases into a consolidated trial of liability and six (6) damages trials, all tried together. Trying the first bellwether case in this manner serves no legitimate purpose except to guarantee a verdict based on unavoidable sympathy after hearing serial tales of suffering. This emphasis on sympathy will inhibit an unemotional verdict on the liability issues. Consolidation should not be ordered in this fashion.<sup>53</sup>

Federal Rule of Civil Procedure 42(a) allows for the consolidation of cases with common questions of law and fact.<sup>54</sup> The party that proposes consolidation bears the burden of showing that consolidation would promote judicial convenience and

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<sup>53</sup> The Tennessee Clinic Defendants are not opposed entirely to the concept of consolidating some aspect of these claims into a single trial. For instance, it may be advisable to bifurcate a consolidated trial into liability and damages and try the liability issue in a way to bind a number of cases that allege the same or similar causes of action, and then move to the damages phase if necessary. Because the PSC has filed its motion to set aside Judge Boal's discovery order in favor of an expedited trial and demanded almost immediate argument, not allowing for any conference process, creative options like this have not been discussed by the parties.

<sup>54</sup> FED. R. CIV. P. 42.



economy.<sup>55</sup> Even where common questions of fact and law are present, FRCP 42(a) does not mandate that the court order consolidation.<sup>56 57</sup>

“If there are [common] issues, the court should ‘weigh the prospective benefits of consolidation, in terms of convenience to the parties and judicial economy against the extent of any confusion, delay or prejudice that might result from consolidation.’”<sup>58 59</sup>

Consolidation is inappropriate if it causes prejudice to a party.<sup>60</sup> If the savings to the judicial system are slight, the risk of prejudice to a party must be viewed with even greater scrutiny.<sup>61</sup> Courts should also specifically consider the amount of evidence that would confusingly overlap in a consolidation of individual trials.<sup>62</sup>

In the mass tort context, courts should be cautious in consolidating cases until full and complete discovery has occurred and enough trials have been conducted to appreciate the full nature of the claims.<sup>63</sup>

We are mindful of the dangers of a streamlined trial process in which testimony must be curtailed and jurors must assimilate vast amounts of information. The systemic urge to aggregate litigation must not be allowed to trump our dedication

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<sup>55</sup> *Powell v. Nat'l Football League*, 764 F. Supp. 1351, 1359 (D. Minn. 1991).

<sup>56</sup> *Arroyo v. Chardon*, 90 F.R.D. 603, 605 (D. P.R. 1981).

<sup>57</sup> Although it will not be discussed in depth here, consolidation of individual cases alleging punitive damages implicates due process concerns and potentially violates the tenets of *Philip Morris USA v. Williams*, 549 US 346 (2007).

<sup>58</sup> *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 834 F. Supp. 477, 487 (D. Mass. 1992) (citing *Spirit v. Teachers Ins. & Annuity Ass'n*, 93 F.R.D. 627, 639 (S.D. N.Y. 1982)) (emphasis added).

<sup>59</sup> Notably, the PSC's motion does not analyze any of the factors the Court should consider when deciding whether consolidation is appropriate. In fact, it does not mention Rule 42 at all.

<sup>60</sup> See *Pino-Betancourt v. Hosp. Pavia Santurce*, 928 F. Supp. 2d 393, 395 (D. P.R. 2013); see also *Arnold v. Eastern Air Lines, Inc.*, 712 F.2d 899, 906 (4<sup>th</sup> Cir. 1983) (“considerations of convenience may not prevail where the inevitable consequence to another party is harmful and serious prejudice”); *Baker v. Waterman S.S. Corp.*, 11 F.R.D. 440, 441 (S.D. N.Y. 1951) (finding “a fair and impartial trial to all litigants” is the most important concern when deciding on consolidation).

<sup>61</sup> *Cantrell v. GAF Corp.*, 999 F.2d 1007, 1011 (6<sup>th</sup> Cir. 1993).

<sup>62</sup> *Gilliam v. Fid. Mgmt. & Research Co.*, No. CIV.A. 04-11600NG, 2005 WL 1288105, at \*4 (D. Mass. 2005); *Liberty Lincoln Mercury, Inc. v. Ford Marketing Corp.*, 149 F.R.D. 65, 81 (D. N.J. 1993) (“[w]here the evidence in one case is not relevant to the issues in the other, consolidation would create a likelihood of prejudice by confusing the issues”).

<sup>63</sup> See *In re Bristol-Myers Squibb Co.*, 975 S.W.2d 601, 603 (Tex. 1998).



to individual justice, and we must take care that each individual plaintiff's – and defendant's – cause not be lost in the shadow of a towering mass litigation.<sup>64</sup>

The PSC made little effort to carry their burden to establish that consolidation is appropriate. The PSC's Motion and supporting Memorandum simply state their proposal to consolidate the cases, with no treatment of the factors necessary for consolidation. They offer no argument why this would promote overall judicial convenience and economy without compromising fairness to the individual parties. The request should be denied because they have not met (nor attempted to meet) their burden.

Notwithstanding the PSC's blatant failure to address the factors for consolidation, the proposal is highly prejudicial to Defendants and would be very confusing for the jury.

Acceptance of the PSC proposal would combine six (6) versions of personal injury before the same jury. This gallery of suffering drawn from the most sympathetic cases is manifestly unfair to the Defendants and assures a reservoir of compassion for the collective Plaintiffs that will overshadow the liability issues. The result is not a fair trial, nor is this how Rule 42 was intended to be applied.<sup>65</sup>

Additionally, the jury would be confused by presenting already complex medical testimony six (6) times in six (6) different cases. The jury would hear medical testimony on multiple Plaintiffs' conditions and prognoses (plus causation testimony), each different, and each requiring separate consideration by the jury. For instance, Mr. Rybinski and Ms. Reed had different fungal infections, indicating different sources of contamination. Mr. McElwee had meningitis; Mr. Ziegler had a local infection; and, Ms.

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<sup>64</sup> *In re Brooklyn Navy Yard Asbestos Litig.*, 971 F.2d 831, 853 (2<sup>nd</sup> Cir. 1992).

<sup>65</sup> See e.g., *Gilliam*, 2005 WL 1288105, at \*4 (denying trial consolidation due to likelihood of jury confusion); see also *Figueroa v. DiNitto*, No. CIV.A. 03-186 ML, 2003 WL 23142193, at \*3 (D. R.I. 2003) (refusing to consolidate Plaintiff's multiple suits because second action added new defendants and brought different claims for relief).

Sullivan had a stroke – three different diagnoses and three different pathologies. The jury will have difficulty understanding a *single* case, much less *six medically-different* cases presented in a mishmash of proof.

Second, the proof on the six (6) Plaintiffs' causes of action differs.

A perfect example is the informed consent claim. The Plaintiffs contend that the injecting physician failed to provide sufficient information so that a reasonable person could make an informed decision to have the injection.<sup>66</sup> Dr. Culclasure did not perform the injections in two (2) of the six (6) cases, and the individual physicians who did perform those two (2) injections are not defendants. In *Ziegler*, Dr. Culclasure is not a defendant. Thus, the jury will be asked to consider informed consent claims where the operative facts for each Plaintiff differ widely. This is obviously confusing.

Another example is the Plaintiffs' claim that the Tennessee Clinic Defendants did not promptly notify the Plaintiffs of their exposure and make timely recommendations for treatment.<sup>67</sup> Each Plaintiff's proof will differ on this claim depending on when they were notified, what information they received, how they reacted, and whether any purported delay caused any further injury. No reasonable jury could be expected to segregate these fact-specific inquiries and render six (6) individual verdicts without confusion.

\* \* \* \* \*

The PSC has not explained why consolidation is appropriate because they cannot do so. Consolidating the cases in the way the PSC proposes serves little

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<sup>66</sup> Master Compl., ¶ 232.

<sup>67</sup> Master Compl., ¶ 234(v).

purpose beyond severely prejudicing the Defendants, confusing the jury, and leading to a highly unpredictable jury verdict.<sup>68</sup>

**e. Defendants' proposal**

The Tennessee Clinic Defendants preliminarily propose a bellwether process that selects four (4) representative STOPNC cases and three (3) representative SSC cases for trial beginning in late-2016 or early-2017<sup>69</sup>:

- Each "side"<sup>70</sup> proposes eight (8) potential bellwether trial cases, creating a pool of 16 potential bellwether trial cases.<sup>71</sup>
- Each "side" can strike four (4) of the other side's eight (8) cases, resulting in a pool of eight (8) potential bellwether trial cases.<sup>72</sup>
- From the remaining eight (8), the parties will either agree upon the four (4) to be tried and the order, or the Court is called upon to make the decision.<sup>73</sup>

This framework is just that – a framework. The parties should collaborate and refine the framework into a written protocol, with the Court's guidance, just as contemplated by Judge Boal's standing discovery order. The PSC's request to set aside Judge Boal's bellwether process in favor of a single, consolidated trial of six (6) non-representative cases is a transparent attempt to deprive the Defendants of a fair trial.

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<sup>68</sup> The PSC's proposal also results in only one finding on liability. A single finding on liability does little to predict future case results. There must be several findings on liability to provide statistically significant data upon which to draw predictive conclusions.

<sup>69</sup> Admittedly, there are details with this proposal that still need to be worked out, such as whether or how alternate cases should be chosen. The PSC's premature filing of the instant motion has diverted the time and attention of the parties from working toward a bellwether selection process that accounts for such details. Under Judge Boal's Order, the parties should be conferring now on a bellwether process, not briefing the PSC's impossible trial proposal.

<sup>70</sup> This will depend on which entities are participating in the bellwether trials, which is not decided at this point, yet another reason the PSC's Motion to Set is premature.

<sup>71</sup> For the SSC cases, the Defendants anticipate each side would propose six (6) potential bellwether trial cases.

<sup>72</sup> For the SSC cases, each side would be permitted three (3) strikes, resulting in a pool of six (6) cases.

<sup>73</sup> For the SSC cases, three (3) cases would be chosen for case-specific discovery and trial.

## **5. Conclusion and relief requested**

The Defendants and PSC have the same interest in the moving this litigation toward a close. However, the realities of this litigation cannot be ignored. The PSC proposes an implausible discovery schedule that ignores the dozens of depositions required at each step. If the Court enters the PSC's proposed order, the cases will be inadequately prepared for trial because it allots insufficient time for complete discovery.

The PSC also proposes to set aside Judge Boal's reasoned approach and instead try six non-representative cases in a single setting. No legal support is offered for this approach. The PSC's proposed consolidated trial is nothing more than an attempt to try six of the PSC's best cases in a fashion that compounds the damages proof and minimizes any consideration of liability.

The PSC's proposal is unreasonable in its timing, and ends with an unfair trial that defies all learned instruction to orderly select and try representative cases. It should not be entered. The Tennessee Clinic Defendants request that the PSC's Motion be denied. The Tennessee Clinic Defendants offer a thorough and fair alternative that is consistent with Judge Boal's prior discovery order. If the Court is inclined to set aside Judge Boal's order – as the PSC asks it to do – the Court should order a timeline and outline of a process similar to that presented in this Response.

## **Oral Argument Requested**

The decision on this motion is obviously important to the way the cases against the Tennessee Clinic Defendants unfold. Thus, the Defendants request oral argument on the Motion.

Respectfully submitted,

**GIDEON, COOPER & ESSARY, PLC**

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**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 30<sup>th</sup> day of March, 2015.

/s/ Chris J. Tardio

**Chris J. Tardio**